

Remarks

Claims 1-16 were pending in this application and rejected by the Examiner. With entry of this response, claims 2-16 have been amended. No claims have been added or deleted.

Objection to the specification

The Examiner objected to the drawings because the figures were not labeled. Applicants have attached a copy of the figures that were filed with this application. Applicants do not know what labels the Examiner is referring to, as the figures appear to be properly labeled and described. Thus, Applicants respectfully request that the Examiner clarify what labels are missing from the figures.

Objection to the claims

Applicants have inserted commas in the locations requested by the Examiner.

Indefiniteness Rejection

The Examiner rejected claims 4, 6, and 13 as allegedly being indefinite for reciting “about” with respect to certain ranges in the claims. Applicants contend that one of skill in the art understands the minor variations on either end of a claimed range that will be encompassed by this term. However, to further prosecution of this case, Applicants have removed the term from the claims. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Enablement Rejections

The Examiner rejected claims 1-8 under 35 U.S.C. §112 as allegedly lacking enablement. The present invention is directed to a novel method of regenerating wheat

plants from transformed wheat tissue. The Examiner, however, contends that specification does not enable any methods of regenerating wheat plants (for varieties other than Bobwhite) following particle bombardment. In support of this contention, the Examiner cites a 1992 (Klein) publication that describes some factors that were identified to improve wheat tissue viability/regenerability following bombardment. The Examiner also contends that the specification does not enable any method of regenerating wheat plants (for any variety) following Agrobacterium transformation. As evidence to support this contention, the Examiner cites a 2003 publication that reports several factors can influence the regenerability of plants from Agrobacterium-transformed wheat tissue. Relying on both of these articles, the Examiner concludes,

undue trial and error experimentation would have been required . . . to use the method of producing any transgenic wheat plant . . . using the method of the claimed invention via particle bombardment [or] via Agrobacterium-mediated transformation and to optimize the parameters for each genotype that will lead to high DNA delivery and decrease tissue damage following inoculation with Agrobacterium and bombardment.

Office Action, pages 6-7.

Applicants disagree. The relevant inquiry for determining enablement is whether one of skill in the art could make and use the claimed invention without undue experimentation. This analysis must consider both the teachings in the application and the knowledge available in the art. It is not necessary for Applicants to describe information that was already known in the art. Additionally, a large quantity of experimentation is permissible, so long as it is *routine*.

The enablement challenge posed by the examiner is whether one of skill in the art, using the knowledge in the art and guidance from the specification, could use Applicants claimed methods to regenerate wheat plants from agro-infected or particle-bombarded wheat tissue without undue experimentation.

None of the evidence cited by the Examiner suggests that undue experimentation would be required to make and use the claimed invention. Quite to the contrary, the Examiner's evidence concerning enablement describes the routine nature of wheat regeneration from bombarded or Agro-infected wheat tissue, while offering some guidance as to how one of skill in the art might further improve those methods. Thus, the combination of knowledge in the art and teachings in the specification enable the present claims.

In the present specification, Applicants provide a detailed methodology for particle bombardment and regeneration using a variety of wheat (Bobwhite) that is an established model for wheat research. Using this knowledge, one of skill in the art can readily make and use the claimed invention with other varieties of wheat. Particle bombardment and Agro-infection of wheat is a common-place laboratory technique that is well within the skill of the art. No undue experimentation is required to simply substitute other varieties of wheat in place of the variety exemplified by Applicants. Nor is there any evidence suggesting that other varieties of wheat cannot be transformed via bombardment or Agro-infection. And as the Examiner has pointed out, the knowledge in the art (as recognized in the cited publications) provides further guidance as to various factors that may be considered when using other varieties of wheat.

Once the skilled artisan has utilized the appropriate transformation protocol, the present invention provides additional knowledge for regenerating that tissue by producing multiple buds. As the examiner notes on page 3-4 of the Office Action, the specification provides an extensive array of relevant teachings on this point. For example, comparisons and analyses using different explants, media components, lighting conditions, timing considerations, etc in Applicants' novel regeneration scheme are provided. In addition, Applicants show actual working embodiments of the present invention by regenerating several different wheat varieties - three spring elite lines (252BW012, N92-0248, Autry525), Bobwhite, and a winter elite line (X-90-37A). Using this knowledge, one of skill in the art can readily apply the invention to other varieties of wheat. In fact, the specification teaches that the "present invention is genotype independent, as multiple genotypes were successfully utilized in corn, cotton, rice and

wheat.” (Page 8, lines 15-21). Again, no undue experimentation is required to simply utilize the present invention with other varieties of a single crop (i.e., wheat).

The publications cited by the Examiner also support the enablement of the present claims. For example, as early as 1992 (*10 years prior to Applicants filing date*), Kleiss reported that transformed (bombarded) wheat could be routinely regenerated into plants. The article highlights improvements to the regeneration protocol that further enhance the results. But these optimization factors do not prevent regeneration or require undue experimentation. Rather, the author has provided guidance to improve the known methods of regenerating wheat after transformation takes place. Furthermore, the article fails to take into account the subsequent decade of research relating to wheat transformation and regeneration. Thus, Kleiss provides some factors that may be optimized via routine experimentation and ultimately supports the enablement of the present claims.

Similarly, Wu describes several factors that influence Agro-mediated processes, such as embryo size, duration of pre-culture, inoculation and co-cultivation etc. As with Kleiss, Wu reports the routine regeneration of wheat following Agro-infection and does not teach or suggest the need for undue experimentation to achieve that result. Rather, Wu reports that there are a number of factors that may be optimized to enhance results. Such optimization represents only routine experimentation. The Examiner has offered no explanation as to how such work would constitute an undue experimental burden for one of skill in the art seeking to transform and regenerate wheat.

To summarize, the evidence of record establishes that wheat can be routinely transformed and regenerated using either Agrobacterium or particle bombardment. That evidence describes factors that may be considered to optimize the processes. But such experimentation is routine in nature and does not call into doubt the enablement of Applicants’ presently claimed invention. Moreover, Applicants specification teaches the skilled artisan how to make and use the presently claimed methods with other varieties of wheat. Specific ranges are described, compared, and exemplified for media components. Suitable starting materials are described and exemplified. And success in wheat is reported using a model wheat system. With that guidance, one of skill in the art can readily optimize the media components for other varieties without undue

experimentation. Such adjustments amount to routine optimization. For these reasons, Applicants respectfully request that the Examiner withdraw the enablement rejections.

Respectfully submitted,



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